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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,779	01/02/2001	Gijsbert Johan Jansen	80541	4107

24628 7590 01/10/2005

WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,779	JANSEN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,13-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,13,14,17,18,20 and 22 is/are rejected.
- 7) ☒ Claim(s) 7,15,19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on June 14, 2004. The request for RCE is accepted and is established with the status of the application as follows: the filling date of this RCE is established as January 2, 2001; Applicants' response to the earlier office action filed on August 30, 2004 is considered and has been entered.

Status of the Application

2. The action is in response to the RCE filed on June 14, 2004. Currently claims 1-3, 5-7, 13-15, 17-22 are pending. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in part.
4. The rejections under 35 USC 112, first paragraph written description and scope of enablement) for claims 7, 15, 19 and 21 and rejection under 35 USC 112, second paragraph to claims 6 and 14 are withdrawn in view of amendment and arguments.
5. The rejections under 35 USC 102(e) and 103(a) are withdrawn herein in view of the amendment and new grounds of rejections.
6. The claim objections made in the previous office action are maintained herein with regard to the claims 5, 13, 17, since the claims recite the phrase "selected from a group consisting of". correction is required.

New Grounds of rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3, 5-7, 13-15, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, and 20-21 are confusing for referring to the subject matter in the term "and/or". Thus it is unclear how the claims can simultaneously encompass all of these limitations. The claim should refer to the subject matter in the alternative only, the replacement of the term "and/or" with "or" or the addition of dependent claims are suggested.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-6, 13-14, 17-18, 20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolas et al. (USPN. 5,895,752) in view of Sheiness et al. (USPN. 5,700,636).

Nicholas et al. teach a method of claim 1, for identifying the presence of a bacterium in a sample, wherein Nicholas et al. disclose that the method comprises:

(a) testing said sample by gram-staining on a sample fixed on a glass slide and determining the rod or coccus character of said bacterium and determining the gram-positive bacterium with a coccus character (see col. 3, line 1-15); (c) identifying the presence of the bacterium in a sample (see col. 3, line 9-15).

With regard to claims 2-3, Nicholas et al. teach that said sample is clinical sample comprises mammalian blood (see col. 3, line 28-37);

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With regard to claims 5, 13, 17, Nicholas et al. teach detection of bacteria comprising *Klebsiella pneumonia*, *Pseudomonas aeruginosa*, *E.coli* (rod-like gram-negative bacteria), *Streptococci*, *Enterococcus* (gram-positive chain like coccus) and *staphylococcus aureus* (gram-positive clumb-like coccus type) (see col. 3, line 4-42, table.1, col. 4, line 34-43).

With regard to claim 21, Nicholas et al teach that the method comprises one-step procedure for binding bacteria present in the sample on a microscopic slide (see col. 3, line 1-3).

However, Nicholas did not teach use of hybridization probe and lysis buffer comprising lysozyme or proteinase K for further characterization of the bacteria.

Sheiness et al. teach a method of claims 1, for detecting microorganism in biological sample, wherein Sheiness et al. disclose that the method comprises use of lysis buffer and hybridization probe to capture microorganism and detection of said microorganism (see col. 6, line 49-67, col. 7, 1-21). Sheiness et al. also teach said use of lysis buffer with lysozyme or proteinase K depending on the type of bacteria to be detected (see col.3, line 49-67, col. 9, line 1-31). Sheiness et al. also teach when the bacteria to be detected is streptococcus type, the lysis buffer comprises lysozyme and proteianse K (see col. 10, line 59-67, col. 11, line 1-5). With regard to claims 6, 14, 18, Sheiness et al. teach probes to said nucleic acid of microorganism is selected from ribosomal RNA col. 14, line 24-41); with regard to claim 20, Sheiness et al. teach that said hybridization comprises positive and negative controls (see col. 18, line 45-58).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to use the method for detecting the presence of bacteria based on gram-stain as taught by Nicholas et al. with a step of using hybridization probe and

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lysis buffer as taught by Sheiness et al. for the purpose of developing a sensitive method of detection of a bacterium in a sample. An ordinary practitioner would have been motivated to combine the method of Nicholas et al. with the inclusion of hybridization and lysis buffer because Sheiness et al. explicitly taught the differences in lysing gram-negative and gram-positive bacteria and the lysing conditions to release nucleic acids from rigid cell walls of different types of bacteria (see col.9, line 12-31 col. 5, line 17-36) Sheiness et al. also taught designing capture probes and selection of lysis conditions enhance the sensitivity and specificity of the detection of bacterium in a sample (see col. 14, line 46-56). The ordinary artisan would have a reasonable expectation of success to combine the method for detection of bacterium in a sample based on gram-staining as taught by Nicholas et al. with the hybridization probe and lysis conditions based on gram-stain of bacteria as taught by Sheiness et al. for the purpose of improving the sensitivity and specificity of the detection of a bacterium in a biological sample.

Allowable subject matter

9. Claims 7, 15, 19, 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru

January 5, 2005


JEFFREY FREDMAN
PRIMARY EXAMINER

